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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,215	04/07/2005	Elias Castanas	P/567-129	1523
2352	7590	04/13/2006	EXAMINER	
OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403			LUKTON, DAVID	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/522,215

Applicant(s)

CASTANAS, ELIAS

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-21 and 28-47 is/are pending in the application.
- 4a) Of the above claim(s) 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 28-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Pursuant to the preliminary amendment filed 3/24/06, claims 1-18 & 22-27 have been cancelled, claim 19 amended, and claims 28-47 added. Claims 19-21 and 28-47 are now pending.

Applicants' election of Group 6 is acknowledged. Applicants have offered that the examiner may withdraw claims 19-21 if they are deemed to be non-statutory. As it happens, claims 19-21 are indeed non-statutory. Accordingly, these claims (19-21) will be withdrawn from consideration.

Applicants' attempt to comply with the election of species requirement is acknowledged. The elected disease (to be treated) is prostate cancer. Applicants have offered that the conjugate is "of" testosterone or serum albumin, but without providing any indication as to whether a linker is used, or the point of attachment between the linker and the testosterone, or between the albumin and the testosterone (if no linker is present). Applicants have also offered that the cytoskeleton acting drug might be taxol, but then again it might be taxotere. These elections are not fully responsive. In any case, in view of the new claims, the restriction requirement is modified, as set forth below.



As before, the following abbreviations are used hereinbelow:

S/MP conjugate: a conjugate comprising a steroid and a mammalian protein

CAD: a "cytoskeleton acting drug"

AAA: an antiandrogen or an antiestrogen or an antiprogestin, or all three of the foregoing

. . . .

Restriction to one of the following inventions is required under 35 U.S.C. §121 (the numbering begins with 9 to avoid conflict with the previous numbering system):

9) Claims 28-37, 40, 41, 43, drawn to a method of treating a solid tumor or hematological malignancy, wherein an antiandrogen is not used.

10) Claims 38, 39, 42, drawn to a method of treating a solid tumor or hematological malignancy, wherein an antiandrogen is used.

Claims 44-47 are not grouped. These claims will be joined with the elected group.

The claimed inventions are distinct.

Groups 10 and 9 are related as combination/subcombination. The S/MP conjugate can be used without the antiandrogen. However, in the event that Group 9 is elected, and claims therein found allowable, it is likely that novelty would then accrue to the Group 10 claims, provided also that any limitations

introduced into the Group 9 claims are introduced into the Group 10 claims as well.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group 9 is chosen for initial examination, election of the following is required:

- a) a fully defined conjugate in which it is made clear whether a linker is present, and if so, the point of attachment of the linker to the testosterone. If a linker is not present, the election should make clear the mode of bonding between the testosterone and the albumin;
- b) one of the following: (i) the "CAD" is taxol, or (ii) the "CAD" is taxotere;
- c) one of the following: (i) the composition is detectably labeled, or a compound within the composition is detectably labeled, or (ii) the composition is not detectably labeled, and no compound within the composition is detectably labeled;
- d) the species of mammal from which the albumin has been obtained.
- e) the route of administration (e.g., oral or intravenous);

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In the event that Group 10 is chosen for initial examination, election of the following is required:

- a) a fully defined conjugate in which it is made clear whether a linker is present, and if so, the point of attachment of the linker to the testosterone. If a linker is not present, the election should make clear the mode of bonding between the testosterone and the albumin;
- b) one of the following: (i) the "CAD" is taxol, or (ii) the "CAD" is taxotere;
- c) one of the following: (i) the composition is detectably labeled, or a compound within the composition is detectably labeled, or (ii) the composition is not detectably labeled, and no compound within the composition is detectably labeled;
- d) the species of mammal from which the albumin has been obtained;
- e) the route of administration (e.g., oral or intravenous);
- f) a specific antiandrogen.

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Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in cursive script, reading "D. Lukton".

DAVID LUKTON, PH.D.
PRIMARY EXAMINER